DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington DC 20204

g1405d

JUN 20 2001

WARNING LETTER
ONPLDS 20-01

BY CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Gerry Morrison
President
Morico Foods, Inc.
2102 Kotter Ave.
Evansville, Indiana 47715

Dear Mr. Morrison:

The Food and Drug Administration (FDA) has reviewed the label for Carbolite. Our review reveals that this label causes the above product to be in violation of the Federal Food, Drug, and Cosmetic Act (the Act) and Title 21, Code of Federal Regulations (21 CFR).

This product is misbranded because the label bears the nutrient content claim "Carbolite" that is not authorized by regulation or the Act (Section 403(r)(1)(A)). FDA has defined the nutrient content claim "Lite" by regulation. This definition does not extend to lite in carbohydrate.

The product is further misbranded because the label bears the claim "Zero Carbohydrate" and the statement "Maltitol .... has been omitted from the total carbohydrate content...." Maltitol is a carbohydrate and must be included in the value declared for "Total Carbohydrate" within, as well as, outside of nutrition labeling (Sections 403(a), 403(q) and 21 CFR 101.9(c)(6).

The above violations are not meant to be an all inclusive list of deficiencies on your labels. It is your responsibility to ensure that all of your products are labeled in compliance with the laws and regulations enforced by FDA. You should take prompt action to correct these deviations and prevent their future recurrence. Failure to make prompt corrections could result in regulatory action without further notice. Possible actions include seizure and/or injunction.

As some additional information we question whether "2 pieces (7g)" is an accurate serving size for this product and request your explanation of the basis for this serving size.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken or plan to take to correct the noted violations. Copies of revised labels for the product should be submitted. If corrective actions cannot be completed within 15 working days, state the reason for delay and the time within which corrections will be completed.

You should direct your written reply to me at the Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Nutritional Products, Labeling and Dietary Supplements (HFS-810), 200 C Street, S.W., Washington, D.C. 20204.

Sincerely yours,

/S/

John B. Foret
Director
Division of Compliance
and Enforcement
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition